

REMARKS

Claims 19-38 are currently pending in the application. Claim 19 is withdrawn. Claims 20 and 33 are amended.

The amendments regarding the length of the body are supported by the specification, namely at page 5, lines 20-23 (“... providing a catheter having a distal end adapted for delivering the therapeutic agent, guiding the catheter into the interior of a patient’s heart and disposing the distal end of the catheter against an endocardial wall of the heart...”), page 6, lines 3-5 (“In one practice of the invention, the local delivery of the therapeutic agent is accomplished by transluminal delivery in which the catheter is steered through access at the femoral artery or vein and directed into the heart.”), and at page 8, lines 6-13:

The depicted system 10 is a catheter system that can be guided through vascular access at the femoral artery or vein of a patient until the delivery chamber 14 enters into the interior chambers of the patient’s heart to implant a depot of drug within the myocardium. To that end, the catheter 12 which extends between the delivery chamber 14 and the handle 18 can be approximately 175 cm to 200 cm in length and can include an elongated rotationally rigid, longitudinally flexible body optionally made of woven polyester fibers, stainless steel wires, thermoset or thermoplastic polymers or any other material suitable for use as a catheter shaft. The catheter can have a substantially uniform diameter of approximately 0.025 to 0.100 inches (0.62 to 2.5 mm).

No new matter is added.

THE INVENTION

Applicants’ invention is an apparatus for implanting a therapeutic agent within a tissue wall. It includes an elongate flexible body, a delivery chamber coupled to the distal end and having a space for carrying a plurality of sequentially positioned pellets comprising a therapeutic agent, and a port for releasing the therapeutic agent. It also includes an actuator coupled to the delivery chamber and capable of sequentially driving pellets containing the therapeutic agent

through the port. The distal end is adapted to penetrate a tissue wall so that the therapeutic agent can be delivered and implanted within the tissue wall.

The apparatus can also include a control mechanism coupled to the actuator, which provides control of the actuator, and a steering mechanism for turning the distal end of the apparatus, allowing the user to selectively guide the device through a body lumen. It can also include a lever-action handle coupled to the control mechanism.

The distal end can be dimensionally adapted to allow for transluminal delivery entry into the interior of a patient's heart. It can also include a plunger for driving the therapeutic agent from the delivery chamber, such as a threaded plunger for advancing into the delivery chamber in response to a rotating action, and a ratchet assembly for allowing delivery of the therapeutic agent in discrete amounts.

The delivery chamber can be substantially cylindrical, and adapted to receive and store the therapeutic agent in the form of pellets, for instance, minispheres or pellets having a pointed shape.

THE CITED ART

Wappler (U.S. Pat. No. 2,269,963; "Wappler")

U.S. Pat. No. 2,269,963 to Wappler discloses a device for implanting small solid bodies into the human body, particularly rod-like "radium seeds." The device is generally pistol-like, with a flesh-piercing point and a plunger for discharging the pellets.

As pointed out on page 3 of the action, Wappler fails to disclose that the device has a flexible body, as required by the present claims.

Campbell *et al.* (U.S. Pat. No. Re. 34,936; "Campbell")

Campbell discloses a system for implanting a solid marker in an animal, which includes a rigid hollow tube (col. 4, lines 10-17) with a sharp distal tip to penetrate the skin of the animal, and a plunger to engage the marker and eject it beneath the animal's skin.

Dragan (U.S. Pat. No. 4,457,712; "Dragan")

This reference discloses a dental syringe with a barrel and a plunger, intended to extrude root canal resin into a root canal. The device is generally pistol-like, and includes a reservoir for holding the resin, and a plunger, ratchet pawl and a needle for dispensing the resin.

THE REJECTIONS

Claim Rejections Under 35 U.S.C. § 103

Reconsideration is requested of the rejection of claims 20-27 and 29-38 as defining subject matter that would have been obvious to one of ordinary skill in the art over Wappler. Amended independent claims 20 and 33 both disclose that the elongate flexible body is of a length sufficient to allow for transluminal delivery of a pellet to the tissue wall.

Wappler discloses a device for implanting radium seeds in tissue. As noted in the action, Wappler does not disclose that the elongate body is flexible, and relies on Campbell for this requirement. However, neither Wappler nor Campbell disclose that either device could deliver an implant deep into the interior of a patient's body, as is done during a transluminal procedure. Such a procedure requires that the body be both long enough to snake through the lumen, and also flexible enough to do so. Neither Wappler nor Campbell disclose or suggest a device that is capable of being used in such a procedure.

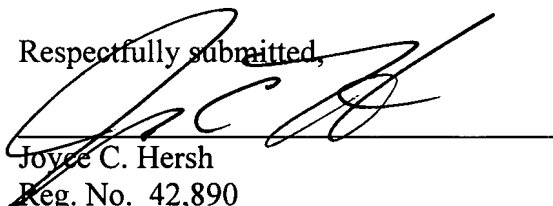
Where neither Wappler and Campbell disclose a device with such characteristics, their combination cannot render such a device obvious. Applicants request that the rejection be reconsidered and withdrawn.

Claim 28 was also rejected as defining subject matter that would have been obvious to one of ordinary skill in the art over Wappler and Dragan, Dragan being relied upon for its disclosure of a threaded plunger.

As discussed above, the claims as amended require that the elongate flexible body be of a length and flexibility sufficient for use in transluminal delivery of the pellets. None of Wappler, Campbell or Dragan disclose such a device, and their combination cannot render the claimed device obvious. Applicants request that the rejection be reconsidered and withdrawn.

Applicants submit that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,



Joyce C. Hersh

Reg. No. 42,890

Attorney for Applicant

KIRKPATRICK & LOCKHART

PRESTON GATES ELLIS LLP

State Street Financial Center

One Lincoln Street

Boston, MA 02111-2950

Tel: 617-261-3100

Fax: 617-261-3175

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